



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,021	02/12/2002	Sang-Nyun Kim	36470-178260	3107

26694 7590 05/28/2004

VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
----------	--------------

1653

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,021

Applicant(s)

KIM ET AL.

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF PRIORITY, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. Acknowledgment is made of Applicant's claim for priority based on Republic of Korea Application Number 2001-7263 having a filing date of 2/14/01. Receipt is acknowledged of papers submitted under U.S.C. §119, which papers have been placed of record in the file. The information disclosure statement (IDS) and Form PTO-1449 filed 2/12/02 are acknowledged, entered and considered. Claims 1 and 2 are present for examination.

CLAIM REJECTION-35 U.S.C. 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. § 102(b) as anticipated by Freed et al. (Transplantation, The Williams & Wilkins Co., Vol. 43, No. 1, pp. 123-127, 1987).

Claim 1 is directed to a hair growth promoter comprising [γ -hydroxy-N-methyl-L-leucine⁹] cyclosporin A as an active ingredient. Freed et al. on page 124, left column, last paragraph define the term "cyclosporin" to refer to all of the metabolites and

Art Unit: 1653

derivatives of cyclosporin A (CsA). On page 123, last paragraph under * Abbreviations used, the reference clearly defines that M1 is a (4-hydroxy-N-methyl—L-leucine⁹) cyclosporin. Similarly, on page 5, second paragraph in the instant specification, Applicant defines M1 as a metabolite wherein a hydroxy group added to a γ carbon of No. 9 residue (MeLeu). The reference teaches the identical compound/composition and would therefore be expected to have the identical properties and function(s).

CLAIMS REJECTION-35 U.S.C. 103(a)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1653

Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Freed et al. (Transplantation, The Williams & Wilkins Co., Vol. 43, No. 1, pp. 123-127, 1987) taken with Elias (U.S. Patent No. 5,807,820).

The instantly claimed invention is directed generally to a hair growth promoter comprising [γ -hydroxy-N-methyl-L-leucine⁹] cyclosporin A as an active ingredient (claim 1), wherein the hair growth promoter is formulated in a form selected from the group consisting of liquid formulation, spray, gel, paste, emulsion, cream, conditioner, and shampoo (claim 2).

The reference of Freed et al. as discussed above on page 124, left column, last paragraph defines the term "cyclosporin" to refer to all of the metabolites and derivatives of cyclosporin A (CsA). On page 123, last paragraph under * Abbreviations used, the reference clearly defines that M1 is a (4-hydroxy-N-methyl—L-leucine⁹) cyclosporin. Similarly, on page 5, second paragraph in the instant specification, Applicant defines M1 as a metabolite wherein a hydroxy group added to a γ carbon of No. 9 residue (MeLeu). As a result, it was found that only the M1 showed an excellent hair growth effect while having reduced immunosuppressiveness. The M1 is named as [γ -hydroxy-N-methyl-L-leucine⁹] cyclosporin A according to the common nomenclature, and its immunosuppressiveness is known to be lower than that of cyclosporin A.

The reference of Freed et al. differs from claims 1 and 2 in not teaching hair growth promoter formulation selected from the group consisting of spray, gel, paste, emulsion, cream, conditioner, and shampoo. However, the primary reference on page 126, paragraph 4, right column states that the data suggest that

although cyclosporines are highly methylated, the particular N-methyl group on amino acid 4 is essential for immunosuppressive activity. We therefore, conclude that the different domains of the cyclosporin molecule are independently involved in conferring biological activity. On the same page and column of 126, on last paragraph, the reference continues by stating the CsA metabolites and other analogues should prove to be valuable tools with which to determine the site of the action of CsA. On page 127, last paragraph, the reference concludes by suggesting that the answer to this question will greatly assist the designing of treatment protocols in the future. Further, the secondary reference of '820 patent teaches the employment of formulations comprising a cyclosporin as an active ingredient for dermal application, especially for the treatment of dermatological diseases, in particular dermatological disease involving morbid proliferation and/or keratinisation of epidermal cells, for use as a hair-growth stimulant, (i.e., for the promotion of hair growth) e.g., for the treatment of alopecia (See e.g., column 1, lines 11 to 17 and col. 2, lines 11 to 12 and the abstract) as directed to claim 1. Thus, given the general teachings of the primary reference (i.e., use of metabolites and derivatives of cyclosporin A, particularly M1 [γ -hydroxy-N-methyl-L-leucine⁹] which its immunosuppressiveness is known to be lower than that of cyclosporin A); one of ordinary skill in the art would have easily selected the claimed specific compound of cyclosporin A (i.e., [γ -hydroxy-N-methyl-L-leucine⁹]) of Freed et al. to be employed as an active ingredient in the secondary reference of '820 patent for the intended purpose of using it as a hair growth promoting formulation because of its known properties which showed excellent hair growth effect while having reduced immunosuppressiveness.

With respect to the limitations of claim 2 wherein the hair growth promoter is formulated in a form selected from the group consisting of liquid formulation, spray, gel, paste, emulsion, cream, conditioner, and shampoo; the secondary reference of '820 patent on Examples 1-5 discloses various formulations suitable for dermal application, e.g., in the treatment of dermatitides or for the stimulation of hair growth. Example 1 provide a formulation which is a gel suitable for topical application, Example 2 provide a formulation which is an ointment or jelly, Example 3 provide a formulation which is an emulsion gel, Example 4 provide a formulation which is a cream, and Example 5 provide a formulation which is an ointment. Further, Example 10, demonstrates the promotion of hair growth in hairless rats. Thus, the reference clearly discloses formulations comprising cyclosporin A and its derivatives in various form for promotion of hair growth, and as such meets the limitations of claim 2.

Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art at the time the invention was made would have been motivated to employ the cyclosporin A of Freed et al., particularly M1 [γ -hydroxy-N-methyl-L-leucine⁹] which its immunosuppressiveness is known to be lower than that of cyclosporin A into the method of the secondary reference of '820 patent which uses a formulation of cyclosporin as an active agent for the promotion of hair growth in the manner claimed in claims 1 and 2, absent of sufficient objective factual evidence or unexpected results to the contrary.


CONCLUSION AND FUTURE CORRESPONDENCE

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

 Mohamed/AAM

May 19, 2004